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Practitioner's Docket No. U 016018-5

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PATENT TRADEMARK OFFICE

CHAPTER II

**TRANSMITTAL LETTER  
TO THE UNITED STATES ELECTED OFFICE (EO/US)  
(ENTRY INTO U.S. NATIONAL PHASE UNDER CHAPTER II)**

INTERNATIONAL APPLICATION NO. PCT/CN2004/000458	INTERNATIONAL FILING DATE 05 SEPTEMBER 2004	PRIORITY DATE CLAIMED 05 OCTOBER 2003
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## TITLE OF INVENTION

RECOMBINANT GENE MEDICINE OF ADENOVIRUS VECTOR AND GENE p53 FOR  
TREATING PROLIFERATIVE DISEASES

## APPLICANT(S)

1. PENG, Zhaohui,
2. ZHANG, Xiaozhi

**Mail Stop PCT**  
**Commissioner for Patents**  
**P. O. Box 1450**  
**Alexandria, VA 22313-1450**

ATTENTION: EO/US

**CERTIFICATION UNDER 37 C.F.R. 1.10\****(Express Mail label number is mandatory.)**(Express Mail certification is optional.)*

I hereby certify that this correspondence and the documents referred to as attached therein are being deposited with the United States Postal Service on this date November 10, 2005, in an envelope as "Express Mail Post Office to Addressee," Mailing Label Number EV 480 462 141 US, addressed to the: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

GERALDINE MARTI

*(Type or print name of person mailing paper)*

Signature of person mailing paper

**WARNING:** Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

**\*WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).  
"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

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**NOTE:** To avoid abandonment of the application, the applicant shall furnish to the USPTO, not later than the expiration of 30 months from the priority date: (1) a copy of the international application, unless it has been previously communicated by the International Bureau or unless it was originally filed in the USPTO; and (2) the basic national fee (see 37 C.F.R. § 1.492(a)). The 30-month time limit may not be extended. 37 C.F.R. § 1.495(a) and (b).

**WARNING:** Where the items are those which can be submitted to complete the entry of the international application into the national phase are subsequent to 30 months from the priority date the application is still considered to be in the international state and if mailing procedures are utilized to obtain a date the express mail procedure of 37 C.F.R. § 1.10 must be used (since international application papers are not covered by an ordinary certificate of mailing - See 37 C.F.R. § 1.8.

**NOTE:** Documents and fees must be clearly identified as a submission to enter the national state under 35 USC 371 otherwise the submission will be considered as being made under 35 USC 111. 37 C.F.R. § 1.494(f).

1. Applicant herewith submits to the United States Elected Office (EO/US) the following items under 35 U.S.C. 371:

- a. ☒ This express request to immediately begin national examination procedures (35 U.S.C. 371(f)).
- b. ☒ The U.S. National Fee (35 U.S.C. 371(c)(1)) and other fees (37 C.F.R. § 1.492) as indicated below:
- c. ☐ **ADDED PAGES FOR APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED**

**NOTE:** § 1.495 Entering the national stage in the United States of America.

(a) The applicant in an international application must fulfill the requirements of 35 U.S.C. 371 within the time periods set forth in paragraphs (b) and (c) of this section in order to prevent the abandonment of the international application as to the United States of America. The thirty month time period set forth in paragraphs (b), (c) (d), (e) and (h) of this section may not be extended. International applications for which those requirements are timely fulfilled will enter the national stage and obtain an examination as to the patentability of the invention in the United States of America.

(b) To avoid abandonment of the application, the applicant shall furnish to the United States Patent and Trademark Office not later than the expiration of thirty months from the priority date:

(1) A copy of the international application, unless it has been previously communicated by the International Bureau or unless it was originally filed in the United States Patent and Trademark Office; and

(2) The basic national fee (see § 1.492(a)).

(c)(1) If applicant complies with paragraph (b) of this section before expiration of thirty months from the priority date, the Office will notify the applicant if he or she has omitted any of:

(i) A translation of the international application, as filed, into the English language, if it was originally filed in another language (35 U.S.C. 371(c)(2));

(ii) The oath or declaration of the inventor (35 U.S.C. 371(c)(4) and § 1.497), if a declaration of inventorship in compliance with § 1.497 has not been previously submitted in the international application under PCT Rule 4.17 (iv) within the time limits provided for in PCT Rule 26ter.1;

(iii) The search fee set forth in § 1.492(c); and

(iv) The examination fee set forth in § 1.492(c); and

(v) Any application size fee required by § 1.492(j)

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(2) A notice under paragraph (c)(1) of this section will set a period of time within which applicant must provide any omitted translation, oath or declaration of the inventor, search fee set forth in § 1.492(b), examination fee set forth in § 1.492(c), and any application size fee required by § 1.492(j) in order to avoid abandonment of the application.

(3) The payment of the processing fee set forth in § 1.492(i) is required for acceptance of English translation later than the expiration of thirty months after the priority date. The payment of the surcharge set forth in § 1.429(h) is required for acceptance of the oath or declaration the inventor later than the expiration of thirty months after the priority date.

## 2. Fees

CLAIMS FEE *	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
	TOTAL CLAIMS*	9 - 20 =		x \$ 50.00 =	\$
	INDEPENDENT CLAIMS*	1 - 3 =		x \$ 200.00 =	
	MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$360.00				
FILING FEES**	<input checked="" type="checkbox"/> Basic filing Fee <input checked="" type="checkbox"/> Non-U.S. Search Report filed (\$400.00) <input type="checkbox"/> No Search Report (\$500.00) <input checked="" type="checkbox"/> Exam Fee not paid to U. S. (\$200.00) <input type="checkbox"/> Search and Exam fee with U.S. WO or IPER conditions not satisfied (\$100.00) <input type="checkbox"/> Search and Exam fee with U.S. WO or IPER conditions satisfied (\$0.00)  <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in electronic medium). The fee is \$250 for each additional 50 sheets paper or fraction thereof (\$ )				\$300.00
	Total of above Calculations				\$ 900.00
SMALL ENTITY	Reduction by ½ for filing by small entity, if applicable. Statement may also be filed. (note 37 CFR 1.9, 1.27, 1.28)				-
	Subtotal				
	Total National Fee				\$ 900.00
	Fee for recording the enclosed assignment document \$40.00 (37 CFR 1.21(h)). (See Item 13 below). See attached "ASSIGNMENT COVER SHEET".				
TOTAL	Total Fees enclosed				\$ 900.00

\*May include Preliminary Amendment (see page 8) reducing the number of claims.

- i. ☒ A check in the amount of \$ 900.00 to cover the above fees is enclosed.
- ii. ☐ Please charge Account No. 12-0425 in the amount of \$  
A duplicate copy of this sheet is enclosed.

**\*\*WARNING:** "To avoid abandonment of the application the applicant shall furnish to the United States Patent and Trademark Office not later than the expiration of 30 months from the priority date: \* \* \* (2) the basic national fee (see § 1.492(a)). The 30-month time limit may not be extended." 37 C.F.R. § 1.495(b).

**WARNING:** If the translation of the international application and/or the oath or declaration have not been submitted by the applicant within thirty (30) months from the priority date, such requirements may be met within a time period set by the Office. 37 C.F.R. § 1.495(b)(2). The payment of the surcharge set forth in § 1.492(e) is required as a condition for accepting the oath or declaration later than thirty (30) months after the priority date. The payment of the processing fee set forth in § 1.492(f) is required for acceptance of an English translation later than thirty (30) months after the priority date. Failure to comply with these requirements will result in abandonment of the application. The provisions of § 1.136 apply to the period which is set. Notice of Jan. 3, 1993, 1147 O.G. 29 to 40.

☐ Assertion of Small Entity Status

☐ Applicant hereby asserts status as a small entity under 37 C.F.R. § 1.27 by.

☐ a Statement or Written Assertion attached.

☐ fee payment

**NOTE:** 37 C.F.R. § 1.27(c) deals with the assertion of small entity status, whether by a written specific declaration thereof or by payment as a small entity of the basic filing fee or the fee for the entry into the national phase as states:

"(c) Assertion of small entity status. Any party (person, small business concern or nonprofit organization) should make a determination, pursuant to paragraph (f) of this section, of entitlement to be accorded small entity status based on the definitions set forth in paragraph (a) of this section, and must, in order to establish small entity status for the purpose of paying small entity fees, actually make an assertion of entitlement to small entity status, in the manner set forth in paragraph (c)(1) or (c)(3) of this section, in the application or patent in which such small entity fees are to be paid.

(1) Assertion by writing. Small entity status may be established by a written assertion of entitlement to small entity status. A written assertion must:

(i) Be clearly identifiable;

(ii) Be signed (see paragraph (c)(2) of this section); and

(iii) Convey the concept of entitlement to small entity status, such as by stating that applicant is a small entity, or that small entity status is entitled to be asserted for the application or patent. While no specific words or wording are required to assert small entity status, the intent to assert small entity status must be clearly indicated in order to comply with the assertion requirement.

(2) Parties who can sign and file the written assertion. The written assertion can be signed by:

(i) One of the parties identified in §§ 1.33(b) (e.g., an attorney or agent registered with the Office), §§ 3.73(b) of this chapter notwithstanding, who can also file the written assertion;

(ii) At least one of the individuals identified as an inventor (even though a §§ 1.63 executed oath or declaration has not been submitted), notwithstanding §§ 1.33(b)(4), who can also file the written assertion pursuant to the exception under §§ 1.33(b) of this part; or

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(iii) *An assignee of an undivided part interest, notwithstanding §§ 1.33(b)(3) and 3.73(b) of this chapter, but the partial assignee cannot file the assertion without resort to a party identified under §§ 1.33(b) of this part.*

(3) *Assertion by payment of the small entity basic filing or basic national fee. The payment, by any party, of the exact amount of one of the small entity basic filing fees set forth in §§ 1.16(a), (f), (g), (h), or (k), or one of the small entity basic national fees set forth in §§ 1.492(a)(1), (a)(2), (a)(3), (a)(4) or (a)(5), will be treated as a written assertion of entitlement to small entity status even if the type of basic filing or basic national fee is inadvertently selected in error.*

(i) *If the Office accords small entity status based on payment of a small entity basic filing or basic national fee under paragraph (c)(3) of this section that is not applicable to that application, any balance of the small entity fee that is applicable to that application will be due along with the appropriate surcharge set forth in §§ 1.16(e) or §§ 1.16(f).*

(ii) *The payment of any small entity fee other than those set forth in paragraph (c)(3) of this section (whether in the exact fee amount or not) will not be treated as a written assertion of entitlement to small entity status and will not be sufficient to establish small entity status in an application or a patent."*

3. ☒ A copy of the International application as filed (35 U.S.C. 371(c)(2)):

*NOTE: Section 1.495 (b) was amended to require that the basic national fee and a copy of the international application must be filed with the Office by 30 months from the priority date to avoid abandonment "The International Bureau normally provides the copy of the international application to the Office in accordance with PCT Article 20. At the same time, the International Bureau notifies applicant of the communication to the Office. In accordance with PCT Rule 47.1, that notice shall be accepted by all designated offices as conclusive evidence that the communication has duly taken place. Thus, if the applicant desires to enter the national stage, the applicant normally need only check to be sure the notice from the International Bureau has been received and then pay the basic national fee by 30 months from the priority date." Notice of Jan. 7, 1993, 1147 O.G. 29 to 40, at 35-36. See item 14c below.*

- a. ☐ is transmitted herewith.
- b. ☐ is not required, as the application was filed with the United States Receiving Office.
- c. ☒ has been transmitted
- i. ☒ by the International Bureau.  
Date of mailing of the application (from form PCT/IB/308): \_\_\_\_\_
- ii. ☐ by applicant on \_\_\_\_\_  
Date

4. ☒ A translation of the International application into the English language (35 U.S.C. 371(c)(2)):

- a. ☒ is transmitted herewith.
- b. ☐ is not required as the application was filed in English.
- c. ☐ was previously transmitted by applicant on \_\_\_\_\_  
Date
- d. ☐ will follow.

*NOTE: 37 C.F.R. § 1.495(c): "If applicant complies with paragraph (b) of this section before expiration of thirty months from the priority date but omits . . . a translation of the international application, as filed, into the English language, if it was originally filed in another language (35 U.S.C. 371(c)(2)) . . . applicant will be so notified and given a period of time within which to file the translation . . . in order to prevent abandonment of the application. The payment of the processing fee set forth in § 1.492(f) is required for acceptance of an English translation later than the expiration of thirty months after the priority date . . . A 'Sequence Listing' need not be translated if the 'Sequence Listing' complies with PCT Rule 12.1(d) and the description complies with PCT Rule 5.2(b)."*

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5. ☒ Amendments to the claims of the International application under PCT Article 19 (35 U.S.C. 371(c)(3)):

*NOTE: The Notice of January 7, 1993 points out that 37 C.F.R. § 1.495(a) was amended to clarify the existing and continuing practice that PCT Article 19 amendments must be submitted by 30 months from the priority date and this deadline may not be extended. The Notice further advises that: "The failure to do so will not result in loss of the subject matter of the PCT Article 19 amendments. Applicant may submit that subject matter in a preliminary amendment filed under section 1.121. In many cases, filing an amendment under section 1.121 is preferable since grammatical or idiomatic errors may be corrected." 1147 O.G. 29-40, at 36.*

*NOTE: 37 C.F.R. § 1.495(d): "A copy of any amendments to the claims made under PCT Article 19, and a translation of those amendments into English, if they were made in another language, must be furnished not later than the expiration of thirty months from the priority date. Amendments under PCT Article 19 which are not received by the expiration of thirty months from the priority date will be considered to be canceled."*

- a. ☐ are transmitted herewith.
  - b. ☐ have been transmitted
    - i. ☐ by the International Bureau.  
Date of mailing of the amendment (from form PCT/IB/308): \_\_\_\_\_
    - ii. ☐ by applicant on \_\_\_\_\_  
Date \_\_\_\_\_
  - c. ☒ have not been transmitted as
    - i. ☒ applicant chose not to make amendments under PCT Article 19.  
Date of mailing of Search Report (from form PCT/ISA/210): 05 August 2004
    - ii. ☐ the time limit for the submission of amendments has not yet expired.  
The amendments or a statement that amendments have not been made will be transmitted before the expiration of the time limit under PCT Rule 46.1.
6. ☒ A translation of the amendments to the claims under PCT Article 19 (38 U.S.C. 371(c)(3)):
- a. ☐ is transmitted herewith.
  - b. ☐ will follow
  - c. ☐ is not required as the amendments were made in the English language.
  - d. ☒ has not been transmitted for reasons indicated at point 5(c) above.
7. ☒ A copy of the international examination report (PCT/IPEA/409)
- ☒ is transmitted herewith.
  - ☐ is not required as the application was filed with the United States Receiving Office.
8. ☐ Annex(es) to the international preliminary examination report
- a. ☐ is/are transmitted herewith.
  - b. ☐ is/are not required as the application was filed with the United States Receiving Office.

9. ☐ A translation of the annexes to the international preliminary examination report

*NOTE: 37 C.F.R. § 1.497(e) "A translation into English of any annexes to an international preliminary examination report (if applicable), if the annexes were made in another language, must be furnished not later than the expiration of thirty months from the priority date. Translations of the annexes which are not received by the expiration of thirty months from the priority date may be submitted within any period set pursuant to paragraph (c) of this section accompanied by the processing fee set forth in § 1.492(f). Annexes for which translations are not timely received will be considered canceled."*

- a. ☐ is transmitted herewith.  
b. ☐ is not required as the annexes are in the English language.

10. ☒ An oath or declaration of the inventor (35 U.S.C. 371(c)(4)) complying with 35 U.S.C. 115

- a. ☐ was previously submitted by applicant on \_\_\_\_\_ Date  
b. ☐ is submitted herewith, and such oath or declaration  
i. ☐ is attached to the application.  
ii. ☐ identifies the application and any amendments under PCT Article 19 that were transmitted as stated in points 3(b) or 3(c) and 5(b); and states that they were reviewed by the inventor as required by 37 C.F.R. 1.70.  
c. ☒ will follow.

*NOTE: 37 C.F.R. § 1.495(c): "If applicant complies with paragraph (b) of this section before expiration of thirty months from the priority date but omits . . . the oath or declaration of the inventor (35 U.S.C. 371(c)(4) and § 1.497), if a declaration of inventorship in compliance with § 1.497 has not been previously submitted in the international application under PCT Rule 4.17(iv) within the time limits provided for in PCT Rule 26ter.1, applicant will be so notified and given a period of time within which to file the . . . oath or declaration in order to prevent abandonment of the application . . . . The payment of the surcharge set forth in § 1.492(e) is required for acceptance of the oath or declaration of the inventor later than the expiration of thirty months after the priority date."*

Other document(s) or information included:

11. ☒ An International Search Report (PCT/ISA/210) or Declaration under PCT Article 17(2)(a):

- a. ☒ is transmitted herewith.  
b. ☐ has been transmitted by the International Bureau.  
Date of mailing (from form PCT/IB/308): \_\_\_\_\_  
c. ☐ is not required, as the application was searched by the United States International Searching Authority.  
d. ☐ will be transmitted promptly upon request.  
e. ☐ has been submitted by applicant on \_\_\_\_\_ Date

12. ☒ An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98:

- a. ☐ is transmitted herewith.  
Also transmitted herewith is/are:  
☐ Form PTO-1449 (PTO/SB/08A and 08B).  
☐ Copies of citations listed.  
b. ☒ will be transmitted within THREE MONTHS of the date of submission of requirements under 35 U.S.C. 371(c).  
c. ☐ was previously submitted by applicant on \_\_\_\_\_ Date

13. ☐ An assignment document is transmitted herewith for recording.

A separate ☐ "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or ☐ FORM PTO 1595 is also attached.

14. ☒ Additional documents:

- a. ☐ Copy of request (PCT/RO/101)  
b. ☒ International Publication No. WO 2004/104204 A1  
i. ☒ Specification, claims and drawing  
ii. ☐ Front page only  
c. ☐ Preliminary amendment (37 C.F.R. § 1.121)  
d. ☒ Other

SUBMISSION OF "SEQUENCE LISTING," COMPUTER READABLE COPY, AND/OR AMENDMENT PERTAINING THERETO FOR BIOTECHNOLOGY INVENTION CONTAINING NUCLEOTIDE AND/OR AMINO ACID SEQUENCE

15. ☒ The above checked items are being transmitted  
a. ☒ before 30 months from any claimed priority date.  
b. ☐ after 30 months.

16. ☐ Certain requirements under 35 U.S.C. 371 were previously submitted by the applicant on \_\_\_\_\_, namely:

#### AUTHORIZATION TO CHARGE ADDITIONAL FEES

**WARNING:** Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges if extra claims are authorized.

**NOTE:** "A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3).

**NOTE:** "Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).

- ☒ The Commissioner is hereby authorized to charge the following additional fees that may be required by this paper and during the entire pendency of this application to Account No. 12-0425.

☒ 37 C.F.R. 1.492(a)(1) (basic filing fee)  
**WARNING:** Because failure to pay the national fee within 30 months without extension (37 C.F.R. § 1.495(b)(2)) results in abandonment of the application, it would be best to always check the above box.

- ☐ 37 C.F.R. 1.492(b) (search fee)  
☐ 37 C.F.R. 1.492(b) (exam fee)  
☐ 37 C.F.R. 1.492(b) (claim fees)



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NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. § 1.492(d)), it might be best not to authorize the PTO to charge additional claim fees, except possible when dealing with amendments after final action.

- ☒ 37 C.F.R. 1.16(s) (spec and drawing, each 50 pages over 100)
- ☒ 37 C.F.R. 1.17 (application processing fees)
- ☒ 37 C.F.R. 1.17(a)(1)-(5) (extension fees pursuant to § 1.136(a).

NOTE: 37 C.F.R. 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying . . . issue fee." From the wording of 37 C.F.R. § 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

- ☐ 37 C.F.R. § 1.492(e) and (f) (surcharge fees for filing the declaration and/or filing an English translation of an International Application later than 30 months after the priority date).
- ☒ Please credit any overpayments to deposit account 12-0425.

SIGNATURE OF PRACTITIONER

CLIFFORD J. MASS

(type or print name of practitioner)

Reg. No.: 30,086

Tel. No.: (212)708-1890

P.O. Address

Customer No.: 00130

c/o Ladas & Parry LLP  
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